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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/665,308	09/19/2000	Rebecca E. Cahoon	BB1149 US NA	5536

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EXAMINER
COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 01/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No.	Applicant(s)	
	09/665,308	CAHOON ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *07 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *91-105* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *91-105* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 27-32, 38-42, 43-48, 54-58, 59-64, 70-74, 75-80, and 86-90, and SEQ ID NOS: 11 and 12, in Paper No. 21 is acknowledged. Claims 27-90 have been cancelled, and claims 91-105 have been newly added. Claims 91-105 are directed to the elected invention of Group I.

Information Disclosure Statement

Initialed and dated copies of Applicant's IDS forms 1449, filed December 22, 2000 and March 26, 2001, Paper Nos. 4 and 7, are attached to the instant Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 91-105 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated polynucleotide comprising a nucleotide sequence encoding a polypeptide having cyclin delta activity wherein the amino acid sequence of the polypeptide has at least 80%, 85%, 90%, 95% or 100% sequence identity with the amino acid

sequence of SEQ ID NO:12, or an isolated polynucleotide comprising a nucleotide sequence of SEQ ID NO:11.

The specification describes a nucleotide sequence of SEQ ID NO:11 encoding an amino acid sequence of SEQ ID NO:12, said nucleotide sequence being a contig of est clones sah1c.pk003.i7 and sr1.pk0001.g5 obtained from soybean cDNA libraries, and said amino acid sequence exhibiting 54% similarity to cyclin delta-1 from *Arabidopsis* (pages 20-22). The specification does not describe any isolated polynucleotide comprising a nucleotide sequence encoding a polypeptide having cyclin delta activity wherein the amino acid sequence of the polypeptide has at least 80%, 85%, 90%, 95% or 100% sequence identity with the amino acid sequence of SEQ ID NO:12. The specification also does not characterize the polypeptide encoded by SEQ ID NO:11 as having cyclin delta activity.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lily and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed product, any method of using it would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No.4/ Friday January 5, 2001/Notices: pp. 1099-1111).

Claim Rejections - 35 USC § 101 and 35 USC § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 91-105 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claims are drawn to an isolated polynucleotide comprising a nucleotide sequence encoding a polypeptide having cyclin delta activity wherein the amino acid sequence has at least 80%, 85%, 90%, 95% or 100% sequence identity with the amino acid sequence of SEQ ID NO:12, or comprising a nucleotide sequence of SEQ ID NO:11.The claims are also drawn to a vector, a recombinant DNA construct, a plant, a seed and a cell comprising said isolated polynucleotide, and to methods for producing a plant and altering the level of expression of a cyclin delta in a host cell.

The specification discloses the cloning of a nucleotide sequence of SEQ ID NO:11 encoding an amino acid sequence of SEQ ID NO:12, said nucleotide sequence being a contig of

est clones sah1c.pk003.i7 and sr1.pk0001.g5 obtained from soybean cDNA libraries, and said amino acid sequence exhibiting 54% similarity to cyclin delta-1 from *Arabidopsis* (pages 20-22). The specification does not disclose any isolated polynucleotide comprising a nucleotide sequence encoding a polypeptide having cyclin delta activity wherein the amino acid sequence of the polypeptide has at least 80%, 85%, 90%, 95% or 100% sequence identity with the amino acid sequence of SEQ ID NO:12. The specification also does not disclose a cyclin delta function for the polypeptide encoded by SEQ ID NO:11. Furthermore, the specification does not disclose the effect of transforming a plant or cell using any of the claimed polynucleotides.

First, the claimed isolated polynucleotide lacks utility because no function has been demonstrated for the polypeptide of SEQ ID NO:12. Although the specification reveals that the amino acid sequence of SEQ ID NO:12 exhibits exhibiting 54% similarity to cyclin delta-1 from *Arabidopsis*, no empirical data is provided to support a cyclin delta-1 function for the polypeptide of SEQ ID NO:12. While empirical data is not required for patentability, the state of the art recognizes that a functional assignment based on sequence comparisons may categorize a protein into a particular class of proteins or provide a starting point for verifying protein activity, it does not replace empirical data for confirming protein activity, as structural homology between amino acid sequences is not always predictive of their functional homology. For example, Doerks et al. teach that incorrect or incomplete sequence information within a database affects the predictive capacity of the database (Trends in Genetics, Vol. 14, No. 6, pages 248-250, see page 248 column 1 paragraph 1). Doerks et al. also teach that query searches may identify shared homology with multiple groups of functionally unrelated proteins (page 248 column 3 second full paragraph), that regions of shared homology may be nonfunctional regions (page 248

column 3 third full paragraph), and that the degree of shared homology within a functional region does not always predict a conservation of the functional mechanism of that region (page 248 column 3 fourth full paragraph).

Second, the claimed isolated polynucleotide lacks substantial utility under current utility guidelines. While the specification asserts that the amino acid sequence of SEQ ID NO:12 is a cyclin delta-1 polypeptide that may function to affect cell growth, the specification does not disclose that the polypeptide of SEQ ID NO:12 exhibits a cyclin delta-1 function, or that expression of the claimed polynucleotides results in altered cell growth. Applicant does not teach how the claimed isolated polynucleotides would be substantially beneficial to the public. Although isolated polynucleotides encoding polypeptides of known function may have a well established utility, isolated polynucleotides encoding polypeptides of unknown function do not. It is apparent that extensive further research, not considered to be routine experimentation, would be required before one of skill in the art would know how to use the claimed invention. It has been established by the courts that a utility which requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use is not a substantial utility.

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." (*Brenner v. Manson*, 383 U.S. 519 (1966)).

Thus, while a polypeptide having a cyclin delta-1 activity has substantial benefit to the public, Applicant does not disclose that a polypeptide of SEQ ID NO:12 has a cyclin delta-1 function, and one skilled in the art cannot conclude that SEQ ID NO:12 has such a function

based upon Applicant's disclosure. Applicant's invention is not refined to the point where specific benefit exists in currently available form. As set forth above, one skilled in the art cannot readily take Applicant's claimed invention and derive immediate benefits from it based upon Applicant's disclosure. Accordingly, the claimed invention lacks a real world use. (see Utility Examination Guidelines published in the Federal Register, Vol. 66, No. 4, Friday, January 5, 2001, Notices, pages 1092-1099).

Claims 91-105 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Results

No claim is allowed.

Claims 91-105 are deemed free of the prior art due to the failure of the prior art to teach or suggest an isolated nucleotide sequence of SEQ ID NO:11 or an amino acid sequence of SEQ ID NO:12.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
December 20, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638